

SCHEDULE 3

PROVISIONS FOR CLASSIFYING DANGEROUS PREPARATIONS

PART II

CONCENTRATION LIMITS TO BE USED IN THE EVALUATION OF HEALTH HAZARDS

An assessment shall be made of the health effects that the use of a substance or a preparation might entail. For that purpose the dangerous health effects have been subdivided into:

1. acute lethal effects;
2. non-lethal irreversible effects after a single exposure;
3. severe effects after repeated or prolonged exposure;
4. corrosive effects, irritant effects;
5. sensitising effects;
6. carcinogenic effects, mutagenic effects, toxic effects for reproduction.

The systematic assessment of the dangerous health effects is expressed by means of concentration limits, expressed as weight/weight percentage except for gaseous preparations (Tables A) where they are expressed as a volume/volume percentage and in conjunction with the classification of a substance.

The classification of the substance is expressed either by a symbol and one or more risk phrases or by categories (category 1, category 2 or category 3) also expressed by risk phrases when substances are shown to be carcinogenic, mutagenic or toxic for reproduction. Therefore it is important to consider, in addition to the symbol, all the phrases denoting specific risks which are assigned to each substance under consideration.

**Acute lethal effects**

1

*Other than gaseous preparations*

1.1 The concentration limits fixed in Table I determine the classification of the preparation in relation to the individual concentration of the substance(s) present whose classification is also shown.

**Table I**

<i>Classification of the substance</i>	<i>Classification of the preparation</i>		
	<i>T+</i>	<i>T</i>	<i>Xn</i>
T+ with R26, R27, R28	concentration ≥ 7%	1% ≤ concentration < 7%	0.1% ≤ concentration < 1%

The R phrases denoting risk shall be assigned to the preparation in accordance with the following criteria—

- (i) the label shall include one or more of the above mentioned R phrases according to the classification used,
- (ii) in general, the R phrases selected should be those applicable to the substance(s) present in the concentration which gives rise to the most severe classification.

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Classification of the substance	Classification of the preparation		
	<i>T+</i>	<i>T</i>	<i>Xn</i>
T with R23, R24, R25		concentration $\geq$ 25%	$3\% \leq$ concentration < 25%
Xn with R20, R21, R22			concentration $\geq$ 25%

The R phrases denoting risk shall be assigned to the preparation in accordance with the following criteria—

- the label shall include one or more of the above mentioned R phrases according to the classification used,
- in general, the R phrases selected should be those applicable to the substance(s) present in the concentration which gives rise to the most severe classification.

### *Gaseous preparations*

1.2 The concentration limits expressed as a volume/volume percentage in Table IA determine the classification of the gaseous preparations in relation to the individual concentrations of the gas(es) present whose classification is also shown.

**Table IA**

Classification of the substance (gas)	Classification of the preparation		
	<i>T+</i>	<i>T</i>	<i>Xn</i>
T+ with R26, R27, R28	concentration $\geq$ 1%	$0.2\% \leq$ concentration < 1%	$0.02\% \leq$ concentration < 0.2%
T with R23, R24, R25		concentration $\geq$ 5%	$0.5\% \leq$ concentration < 5%
Xn with R20, R21, R22			concentration $\geq$ 5%

The R phrases denoting risk shall be assigned to the preparation in accordance with the following criteria—

- the label shall include one or more of the above mentioned R phrases according to the classification used,
- in general, the R phrases selected should be those applicable to the substance(s) present in the concentration which gives rise to the most severe classification.

### **Non-lethal irreversible effects after a single exposure**

2

#### *Other than gaseous preparations*

2.1 For substances that produce non-lethal irreversible effects after a single exposure (R39/route of exposure, R68/route of exposure), the individual concentration limits specified in Table II determine, when appropriate, the classification of the preparation.

**Table II**

<i>Classification of the substance</i>	<i>Classification of the preparation</i>		
	<i>T+</i>	<i>T</i>	<i>Xn</i>
T+ with R39/ route of exposure	concentration $\geq$ 10% R39 <sup>(*)</sup> obligatory	1% $\leq$ concentration < 10% R39 <sup>(*)</sup> obligatory	0.1% $\leq$ concentration < 1% R68 <sup>(*)</sup> <sup>(†)</sup> obligatory
T with R39/ route of exposure		concentration $\geq$ 10% R39 <sup>(*)</sup> obligatory	1% $\leq$ concentration < 10% R68 <sup>(*)</sup> <sup>(†)</sup> obligatory
Xn with R68/ route of exposure			concentration $\geq$ 10% R68 <sup>(*)</sup> <sup>(†)</sup> obligatory

(\*) In order to indicate the route of administration/exposure the combined R phrases listed in Annex III of the Council Directive 67/548/EEC shall be used.

(†) R68 here refers to substances classified as harmful. Concentration limits for substances required to be labelled R68 but classified mutagenic are given in Table VI.

*Gaseous preparations*

2.2 For gases that produce non-lethal irreversible effects after a single exposure (R39/route of exposure, R68/route of exposure), the individual concentration limits specified in Table IIA, expressed as a volume/volume percentage, determine, when appropriate, the classification of the preparation.

**Table IIA**

<i>Classification of the substance (gas)</i>	<i>Classification of the preparation</i>		
	<i>T+</i>	<i>T</i>	<i>Xn</i>
T+ with R39/ route of exposure	concentration $\geq$ 1% R39 <sup>(*)</sup> obligatory	0.2% $\leq$ concentration < 1% R39 <sup>(*)</sup> obligatory	0.02% $\leq$ concentration < 0.2% R68 <sup>(*)</sup> <sup>(†)</sup> obligatory
T with R39/ route of exposure		concentration $\geq$ 5% R39 <sup>(*)</sup> obligatory	0.5% $\leq$ concentration < 5% R68 <sup>(*)</sup> <sup>(†)</sup> obligatory
Xn with R68/ route of exposure			concentration $\geq$ 5% R68 <sup>(*)</sup> <sup>(†)</sup> obligatory

(\*) In order to indicate the route of administration/exposure the combined R phrases listed in Annex III of Council Directive 67/548/EEC shall be used.

(†) R68 here refers to substances classified as harmful. Concentration limits for substances required to be labelled R68 but classified mutagenic are given in Table VI.

**Severe effects after repeated or prolonged exposure**

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#### Other than gaseous preparations

3.1 For substances that produce severe effects after repeated exposure (R48/route of exposure), the individual concentration limits specified in Table III determine, when appropriate, the classification of the preparation.

**Table III**

Classification of the substance	Classification of the preparation	
	T	Xn
T with R48/ route of exposure	concentration $\geq$ 10% R48 <sup>(*)</sup> obligatory	1% $\leq$ concentration < 10% R48 <sup>(*)</sup> obligatory
Xn with R48/ route of exposure		concentration $\geq$ 10% R48 <sup>(*)</sup> obligatory

(\*) In order to indicate the route of administration/exposure the combined R phrases listed in Annex III of Council Directive 67/548/EEC shall be used.

#### Gaseous preparations

3.2 For gases that produce severe effects after repeated or prolonged exposure (R48/route of exposure), the individual concentration limits specified in Table IIIA, expressed as a volume/volume percentage, determine, when appropriate, the classification of the preparation.

**Table IIIA**

Classification of the substance (gas)	Classification of the preparation	
	T	Xn
T with R48/ route of exposure	concentration $\geq$ 5% R48 <sup>(*)</sup> obligatory	0.5% $\leq$ concentration < 5% R48 <sup>(*)</sup> obligatory
Xn with R48/ route of exposure		concentration $\geq$ 5% R48 <sup>(*)</sup> obligatory

(\*) In order to indicate the route of administration/exposure the combined R phrases listed in Annex III of Council Directive 67/548/EEC shall be used.

#### Corrosive and irritant effects including serious damage to eye

4

#### Other than gaseous preparations

4.1 For substances that produce corrosive effects (R34, R35) or irritant effect (R36, R37, R38, R41), the individual concentration limits specified in Table IV determine, when appropriate, the classification of the preparation.

**Table IV**

<i>Classification of the substance</i>	<i>Classification of the preparation</i>			
	<i>C with R35</i>	<i>C with R34</i>	<i>Xi with R41</i>	<i>Xi with R36, R37 R38</i>
C with R35	concentration $\geq 10\%$ R35 obligatory	$5\% \leq$ concentration $< 10\%$ R34 obligatory	$5\%^{(*)}$	$1\% \leq$ concentration $< 5\%$ R36/38 obligatory
C with R34		concentration $\geq 10\%$ R34 obligatory	$10\%^{(*)}$	$5\% \leq$ concentration $< 10\%$ R36/38 obligatory
Xi with R41			concentration $\geq 10\%$ R41 obligatory	$5\% \leq$ concentration $< 10\%$ R36 obligatory
Xi with R36, R37, R38				concentration $\geq 20\%$ R36, R37, R38 are obligatory in the light of the concentration present if they apply to the substances under consideration

(\*) According to the approved classification and labelling guide, when a substance or preparation is classified as corrosive and assigned the risk phrase R34 or R35, the risk of severe damage to the eyes is considered implicit and the risk phrase R41 is not included on the label. Consequently, if the preparation contains corrosive substances with R35 or R34 below the concentration limits for a classification of the preparation as corrosive, such substances can contribute to a classification of the preparation as irritant (R41) or irritant (R36).

**Note**

Simple application of the conventional method to preparations containing substances classified as corrosive or irritant may result in under-classification or over-classification of the hazard, if other relevant factors (e.g. pH of the preparation) are not taken into account. Therefore, in classifying for corrosivity consider the advice given in the approved classification and labelling guide regarding classification as corrosive and paragraph 4(4) (b) and (c) of Part I of this Schedule.

*Gaseous preparations*

4.2 For gases that produce such effects (R34, R35 or R36, R37, R38, R41), the individual concentration limits specified in Table IVA, expressed as a volume/volume percentage determine, when appropriate, the classification of the preparation.

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**Table IVA**

<i>Classification of the substance (gas)</i>	<i>Classification of the preparation</i>			
	<i>C with R35</i>	<i>C with R34</i>	<i>Xi with R41</i>	<i>Xi with R36, R37 R38</i>
C with R35	concentration $\geq 1\%$ R35 obligatory	$0.2\% \leq$ concentration $< 1\%$ R34 obligatory	$0.2\%^{(*)}$	$0.02\% \leq$ concentration $< 0.2\%$ R36/37/38 obligatory
C with R34		concentration $\geq 5\%$ R34 obligatory	$5\%^{(*)}$	$0.5\% \leq$ concentration $< 5\%$ R36/37/38 obligatory
Xi with R41			concentration $\geq 5\%$ R41 obligatory	$0.5\% \leq$ concentration $< 5\%$ R36 obligatory
Xi with R36, R37, R38				concentration $\geq 5\%$ R36, R37, R38 are obligatory as appropriate

(\*) According to the approved classification and labelling guide, when a substance or preparation is classified as corrosive and assigned the risk phrase R34 or R35, the risk of severe damage to the eyes is considered implicit and the risk phrase R41 is not included on the label. Consequently, if the preparation contains corrosive substances with R35 or R34 below the concentration limits for a classification of the preparation as corrosive, such substances can contribute to a classification of the preparation as irritant (R41) or irritant (R36).

**Note**

Simple application of the conventional method to preparations containing substances classified as corrosive or irritant may result in under-classification or over-classification of the hazard, if other relevant factors (e.g. pH of the preparation) are not taken into account. Therefore, in classifying for corrosivity, consider the advice given in approved classification and labelling guide regarding classification as corrosive and paragraph 4(4) (b) and (c) of Part I of this Schedule.

**Sensitising effects**

5

*Other than gaseous preparations*

5.1 Preparations that produce such effects are classified as sensitising and assigned:

- the symbol Xn and phrase R42 if this effect can be produced by inhalation,
- the symbol Xi and phrase R43 if this effect can be produced through contact with the skin.

The individual concentration limits specified in Table V determine, when appropriate, the classification of the preparation.

**Table V**

<i>Classification of the substance</i>	<i>Classification of the preparation</i>	
	<i>Sensitising with R42</i>	<i>Sensitising with R43</i>
Sensitising with R42	concentration $\geq$ 1% R42 obligatory	
Sensitising with R43		concentration $\geq$ 1% R43 obligatory

*Gaseous preparations*

5.2 Gases that produce such effects are classified as sensitising and assigned:

- the symbol Xn and phrase R42 if this effect can be produced by inhalation,
- the symbol Xi and phrase R43 if this effect can be produced by inhalation and through contact with the skin.

The individual concentration limits specified in Table VA expressed as a volume/volume percentage, determine, when appropriate, the classification of the preparation.

**Table VA**

<i>Classification of the substance (gas)</i>	<i>Classification of the gaseous preparation</i>	
	<i>Sensitising with R42</i>	<i>Sensitising with R43</i>
Sensitising with R42	concentration $\geq$ 0.2% R42 obligatory	
Sensitising with R43		concentration $\geq$ 0.2% R43 obligatory

**Carcinogenic/mutagenic/toxic effects for reproduction**

6

*Other than gaseous preparations*

6.1 For substances that produce such effects and for which specific concentration limits do not yet appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation, concentration limits laid down in Table VI shall determine, where appropriate, the classification of the preparation.

The following symbol and risk phrases are assigned:

Carcinogenic categories 1 and 2:	T; R45 or R49
Carcinogenic category 3:	Xn; R40
Mutagenic categories 1 and 2:	T; R46
Mutagenic category 3:	Xn R68
Toxic for reproduction fertility categories 1 and 2:	T; R60

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Toxic for reproduction development categories 1 and 2: T; R61

Toxic for reproduction fertility category 3: Xn; R62

Toxic for reproduction development category 3: Xn; R63

**Table VI**

<i>Classification of the substance</i>	<i>Classification of the preparation</i>	
	<i>Categories 1 and 2</i>	<i>Category 3</i>
carcinogenic substances of category 1 or 2 with R45 or R49	concentration $\geq$ 0.1% carcinogenic R45, R49 obligatory as appropriate	
carcinogenic substances of category 3 with R40		concentration $\geq$ 1% carcinogenic R40 obligatory (unless already assigned R45)
mutagenic substances of category 1 or 2 with R46	concentration $\geq$ 0.1% mutagenic R46 obligatory	
mutagenic substances of category 3 with R68		concentration $\geq$ 1% mutagenic R68 obligatory (unless already assigned R46)
substances “toxic for reproduction” of category 1 or 2 with R60 (fertility)	concentration $\geq$ 0.5% toxic for reproduction (fertility) R60 obligatory	
substances “toxic for reproduction” of category 3 with R62 (fertility)		concentration $\geq$ 5% toxic for reproduction (fertility) R62 obligatory (unless already assigned R60)
substances “toxic for reproduction” of category 1 or 2 with R61 (development)	concentration $\geq$ 0.5% toxic for reproduction (development) R61 obligatory	
substances “toxic for reproduction” of category 3 with R63 (development)		concentration $\geq$ 5% toxic for reproduction (development) R63 obligatory (unless already assigned R61)
<b>a</b>	In cases where the preparation is assigned R49 and R40, both R phrases shall be kept, because R40 does not distinguish between the exposure routes, whereas R49 is only assigned for the inhalation route.	
<b>b</b>	R68 here refers to substances classified as mutagenic. Concentration limits for substances required to be labelled R68 but classified as harmful are given in Table II.	

### *Gaseous preparations*

6.2 For gases which produce such effects and for which specific concentration limits do not yet appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation, concentration limits laid down in Table VIA, expressed as a volume/volume percentage, shall determine, where appropriate, the classification of the preparation.

The following symbol and risk phrases are assigned:



Carcinogenic categories 1 and 2:	T; R45 or R49
Carcinogenic category 3:	Xn; R40
Mutagenic categories 1 and 2:	T; R46
Mutagenic category 3:	Xn R68
Toxic for reproduction fertility categories 1 and 2:	T; R60
Toxic for reproduction development categories 1 and 2:	T; R61
Toxic for reproduction fertility category 3:	Xn; R62
Toxic for reproduction development category 3:	Xn; R63

**Table VIA**

<i>Classification of the substance (gas)</i>	<i>Classification of the gaseous preparation</i>	
	<i>Categories 1 and 2</i>	<i>Category 3</i>
carcinogenic substances of category 1 or 2 with R45 or R49	concentration $\geq$ 0.1% carcinogenic R45, R49 obligatory as appropriate	
carcinogenic substances of category 3 with R40		concentration $\geq$ 1% carcinogenic R40 obligatory ( <i>unless already assigned R45</i> )
mutagenic substances of category 1 or 2 with R46	concentration $\geq$ 0.1% mutagenic R46 obligatory	
mutagenic substances of category 3 with R68		concentration $\geq$ 1% mutagenic R68 obligatory ( <i>unless already assigned R46</i> )
substances “toxic for reproduction” of category 1 or 2 with R60 (fertility)	concentration $\geq$ 0.2% toxic for reproduction (fertility) R60 obligatory	
substances “toxic for reproduction” of category 3 with R62 (fertility)		concentration $\geq$ 1% toxic for reproduction (fertility) R62 obligatory ( <i>unless already assigned R60</i> )
substances “toxic for reproduction” of category 1 or 2 with R61 (development)	concentration $\geq$ 0.2% toxic for reproduction (development) R61 obligatory	
substances “toxic for reproduction” of category 3 with R63 (development)		concentration $\geq$ 1% toxic for reproduction (development)
<b>a</b>	In cases where the preparation is assigned R49 and R40, both R phrases shall be kept, because R40 does not distinguish between the exposure routes, whereas R49 is only assigned for the inhalation route.	
<b>b</b>	R68 here refers to substances classified as mutagenic. Concentration limits for substances required to be labelled R68 but classified as harmful are given in Table IIA.	

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<i>Classification of the substance (gas)</i>	<i>Classification of the gaseous preparation</i>	
	<i>Categories 1 and 2</i>	<i>Category 3</i>
		R63 obligatory ( <i>unless already assigned R61</i> )
<b>a</b>	In cases where the preparation is assigned R49 and R40, both R phrases shall be kept, because R40 does not distinguish between the exposure routes, whereas R49 is only assigned for the inhalation route.	
<b>b</b>	R68 here refers to substances classified as mutagenic. Concentration limits for substances required to be labelled R68 but classified as harmful are given in Table IIA.	